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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,518	07/20/2001	Philip W. Hammond	50036/016003	2840
31020	7590	02/25/2003		
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			EXAMINER	
			SPIEGLER, ALEXANDER H	
		ART UNIT	PAPER NUMBER	
		1637		//
		DATE MAILED: 02/25/2003		

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/910,518	HAMMOND ET AL.
Examiner	Art Unit	
Alexander H. Spiegler	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 16 October 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-17 is/are pending in the application.
 - 4a) Of the above claim(s) 11-17 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-10 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4, 6.

- 4) Interview Summary (PTO-413) Paper No(s) _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I (claims 1-10) in Paper No. 10 is acknowledged.

Applicants argue "Applicants filed the claims of the present divisional application in reliance on the claim grouping made by the U.S. Patent Office in [the] parent case, U.S.S.N. 09/374,962". (pg. 1 of Applicants response) Also, Applicant asserts that the claims of Group II-V were "mistakenly referred to being directed to methods", and that Groups II-V "are in fact also directed to libraries of nucleic acids." (pg. 2 of Applicants response)

Applicant's arguments have been considered, but are not persuasive for the following reasons. First, Applicants argument for regrouping Groups I-V together based on their "reliance" on a previous grouping of claims does not have support in the MPEP. With respect to Applicants second argument, the groups are drawn to different nucleic acid molecules (made by different methods) and have been properly restricted. Claim 1 (Group I) is simply drawn to "a library of nucleic acid molecules, each molecule comprising an open reading frame and lacking the 3'-untranslated region normally associated with said open reading frame". However, in claim 11 (Group II), the DNA molecule undergoes a series of treatment steps that materially alters the structure of the DNA molecule, alterations that are not required by claim 1 (which is not even solely drawn to DNA molecules as is claim 11). Thus, the nucleic acid of Group I and the nucleic acid of Group II are distinct products. The nucleic acid of Group I and the nucleic acids of Groups III-IV are also materially different and distinct products because Group III requires RNA-DNA duplexes and the removal of stop codons (claim 13), Group IV requires the

removal of stop codons and Group V requires random primer extension, which are all not required in Group I. In addition to the distinctness of the nucleic molecules of Groups I-V, an undue search burden exists if all groups were to be searched together. Each group is drawn to specific steps for making the claimed nucleic acid molecules. These different method steps require searching in unrelated areas, for example, Group II requires searching for exonucleases and single-stranded nucleases, Group III requires searching for a "pausing of [a] translation reaction mixture ribosome", Group IV requires searching for Type IIS restriction enzymes and Group V requires searching for primers comprising a 5' region which lacks a stop codon in at least one reading frame and a random 3' region. All of these searches are clearly distinct from the search of Group I.

Finally, it is also noted that while claim 17 was originally grouped together with Group I, after further consideration, it has been determined that claim 17 should be grouped with Group III. It is Group III, not Group I, that requires "translating a library of mRNA molecules comprising open reading frames *in vitro* in a translation reaction mixture lacking functional translation release factor activity" for making the claimed DNA molecule. This language that is found in Group III is also found in claim 17.

Therefore, this restriction is made FINAL. Claims 1-10 have been examined on the merits.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 1-10 are indefinite over "normally associated with said open reading frame" because it is not clear as to what is meant by "normally associated with said open reading frame" or how one determines whether the 3'-untranslated region is "normally associated" with said ORF.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 1-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Szostak et al. (USPN 6214,553).

Szostak teaches methods of making and using libraries of proteins encoding RNA-protein

fusions. Specifically, Szostak teaches populations of RNA-protein fusions can comprise more than one RNA, mRNA, DNA, RNA-protein fusion or any two or more covalently bonded naturally or modified ribonucleotide molecules, and may comprise more than 10^5 members (col. 1-3, col. 4, ln. 63 to col. 5, ln. 3 and col. 5, ln. 17-21). Szostak teaches that the nucleic acid molecule includes an open reading frame (see for example, col. 16, ln. 30-61)

Szostak also teaches that the nucleic molecule can be from a eukaryotic organism or "in principle...any translation system which allows formation of an RNA-protein fusion which does not significantly degrade the RNA portion of the fusion is useful in the invention." (col. 14, ln. 10-48, col. 29, ln. 15-61 and col. 40, ln. 55 to col. 41, ln. 14).

Szostak (col. 41, ln. 59 to col. 42, ln. 22) also teaches:

The RNA-protein fusion technology is also useful for screening cDNA libraries and cloning new genes on the basis of protein-protein interactions. By this method, a cDNA library is generated from a desired source (for example, by the method of Ausubel et al., *supra*, chapter 5). To each of the candidate cDNAs, a peptide acceptor (for example, as a puromycin tail) is ligated (for example, using the techniques described above for the generation of LP77, LP154, and LP160). RNA-protein fusions are then generated as described herein, and the ability of these fusions (or improved versions of the fusions) to interact with particular molecules is then tested as described above. *If desired, stop codons and 3' UTR regions may be avoided in this process* by either (i) adding suppressor tRNA to allow readthrough of the stop regions, (ii) removing the release factor from the translation reaction by immunoprecipitation, (iii) a combination of (i) and (ii), or (iv) removal of the stop codons and 3' UTR from the DNA sequences.

The fact that the interaction step takes place *in vitro* allows careful control of the reaction stringency, using nonspecific competitor, temperature, and ionic conditions. Alteration of normal small molecules with non-hydrolyzable analogs (e.g., ATP vs. ATPgS) provides for selections that discriminate between different conformers of the same molecule. This approach is useful for both the cloning and functional identification of many proteins since the RNA sequence of the selected binding partner is covalently attached and may therefore be readily isolated. In addition, the technique is useful for identifying functions and interactions of the -50-100,000 human genes...

Accordingly, Szostak teaches all of the limitations claimed by the instant application.

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Conclusion

6. No claims are allowable.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (703) 305-0806. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014. Applicant is also invited to contact the TC 1600 Customer Service Hotline at (703) 308-0198.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Alexander H. Spiegler

Alexander H. Spiegler
February 24, 2003

Kenneth R. Horlick
KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

2/24/03